K111676

# 510(k) SUMMARY

SEP 3 0 2011

**Date of preparation of summary:** May 10th 2011

**Submitted by:**
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**Contact name:** Mr Patrick Hull

**Trade Name:** Apex™

**Common Name:** Add-on microMLC

**Classification Name:** BLOCK, BEAM-SHAPING, RADIATION THERAPY (21CFR 892 5710, Product Code IXI)

**Predicate Device:** DMLC IV (K001163)

**Product Description:**
This Traditional 510(k) describes modifications made to the add-on DMLC accessory for the Elekta range of digital linear accelerators. The primary reason for these enhancements is to improve the leaf resolution - Apex™ has a reduced leaf width of 2.5mm and increased field size.

**Intended Use Statement:**

Apex™ is an add-on microMLC system. It is an accessory to the linear accelerator used for radiation therapy and it is intended to shape the X-ray field both in static (fixed) or dynamic mode with rotating gantry as a function of the gantry angle. It is provided to assist the radiation oncologist to deliver radiation to the target tissue while sparing the surrounding normal tissues.

**Indication for Use Statement:**

Apex™ is an add-on microMLC system. It is an accessory to the linear accelerator used for radiation therapy and it is intended to shape the X-ray field both in static (fixed) or dynamic mode with rotating gantry as a function of the gantry angle. It is provided to assist the radiation oncologist to deliver radiation to the target tissue while sparing the surrounding normal tissues.

**Summary of Technological Characteristics:**
The add-on MLC Apex™ consist of a 112 leaves individually controlled and monitored having a 2.5mm thickness at the isocenter and a field size of 120 mm x 140 mm.
There has been no substantial change made to the underlying technological characteristics of the product.

**Substantial Equivalence**
The functionality for the Apex™ is equivalent to its predicate device DMLC IV (K001163) in safety and effectiveness. The fundamental technical characteristics are the same as those of the predicate device and differences in operation are described in the comparison chart and discussion provided elsewhere in this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 24 2012

Mr. Patrick Hull
Regulatory Affairs Engineer
Elekta Limited
Linac House, Fleming Way
CRAWLEY, WEST SUSSEX RH10 9RR
UNITED KINGDOM

Re: K111676
Trade/Device Name: Apex
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation Therapy beam-shaping block
Regulatory Class: II
Product Code: IXI
Dated: May 10, 2011
Received: June 15, 2011

Dear Mr. Hull:

This letter corrects our substantially equivalent letter of September 30, 2011.
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4 - Indications for Use Statement and Technical Description of Apex

510(k) Number (if known): K111676

Device Name: Apex

Indications for Use:

Apex is an add-on microMLC system. It is an accessory to the linear accelerator used for radiation therapy and it is intended to shape the X-ray field both in static (fixed) or dynamic mode with rotating gantry as a function of the gantry angle. It is provided to assist the radiation oncologist to deliver radiation to the target tissue while sparing the surrounding normal tissues.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Mary S Pastel

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~ In Vitro Diagnostics OIVD